

Appl. No. : **09/988,728**
Filed : **November 16, 2001**

REMARKS

Applicant has the following comments and remarks in response to the Office Action.

Discussion of Drawing Changes

In the Office Action, the Examiner objected to the drawings for certain informalities. First, the Examiner stated that the reference sign 128 points to two different channel types. The Examiner suggested that the lines protruding from the number 128 be amended to not touch the channels. Applicant respectfully submits that he has amended Figure 1A in conformance with this suggestion. Furthermore, the Examiner stated that reference signs 134 and 136 are duplicates since the specification defines both as mixing chambers. Applicant respectfully notes that these reference numerals refer to different mixing chambers, and therefore requests withdrawal of this objection.

With respect to Figure 1B, the Examiner stated that reference sign 140 indicates "target zones" on substrate 106, which is not shown in the figure. Applicant notes that the target zones 140 are clearly shown on substrate 106 in Figure 1C. Applicant has corrected Figure 1B to dash out portions that would not be visible from a top-down view. With respect to Figure 1C, the Examiner indicated that chambers 164 should not be visible. Applicant has corrected Figure 1C to show these features in broken lines.

With respect to Figure 1C, the Examiner stated that the chambers 128 should not be visible on the right hand portion of the Figure. Applicant has amended the figure to correct this.

With respect to Figure 2A, the Examiner indicated that the positioning of reference sign 150 is misleading. Applicant has corrected this by the present amendments.

With respect to Figure 2C, the Examiner stated that the chambers 164 should not be visible on the right hand portion of the Figure. Applicant has amended the figure to correct this.

Discussion of Objections to the Specification

In the Office Action, with respect to Claims 6 and 7, the Examiner states that the phrases "discrete capture zone" and "second discrete capture zone" are not recited in the disclosure. Furthermore, with respect to Claim 7, the Examiner stated that term "predetermined pattern" is not disclosed in the specification. The Examiner notes that the term "capture zone" is recited numerous times in the disclosure but not with the limitation of "discrete." Although Applicant

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disagrees with the Examiner's position that literal use of the term "discrete" or "predetermined pattern" is needed to provide proper antecedent basis for such use in the claims, to expedite the prosecution the Applicant has cancelled the "discrete" and "predetermined pattern" limitations from Claims 7 and 17.

Furthermore, with respect to Claim 7 and 17, the Examiner stated that the use of multiple agents was not described in the specification. Applicant notes that the specification describes the usage of multiple agents, such as an antibody or aptamar. Page 8, lines 1-7. The description states that the assays use localized cell capture at capture zones. Page 9, lines 11-12. The cell capture zones are created by localized application of various monoclonal or polyclonal antibodies particular to white blood cell antigens. Page 9, lines 11-15. Furthermore, Applicant notes that the original claims themselves are part of the original specification and thereby serve as description of the claimed subject matter.

With respect to Claim 13, the Examiner took the position that "determining a cell concentration" is not disclosed in the specification. Applicant notes that page 21 line 25- page 22, line 3, describing determining a cell count. Applicant submits that one of ordinary skill in the art can readily determine a concentration based upon a cell count and a known volume. Furthermore, Applicant notes that the original claims themselves are part of the original specification and thereby serve as description of the claimed subject matter.

Discussion of Claim Objections

In the Office Action, the Examiner objected to certain informalities in the claims. Applicant respectfully submits that these have been corrected by the above-amendments.

Discussion of Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

In the Office Action, the Examiner rejected Claims 1 and 4 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, the Examiner stated that the terms "disc surface" and "disc" are unclear and indefinite. The Examiner was unclear whether the discs were the "optical disc" or the "disc drive." Furthermore, the Examiner indicated that the phrase "providing a sample of cells on a disc surface in a chamber in a disc." With respect to Claim 5, the Examiner stated that "any one

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of Claim 1” is confusing and indefinite. Applicant respectfully submits that he has corrected these ambiguities by the above-amendments.

Furthermore, the Examiner noted that there was insufficient antecedent basis for certain limitation in Claims 14, 18, and 21. Applicant has corrected this by the above-amendments.

Discussion of Claim Rejections Under 35 U.S.C. §§ 102(e) and 103(a)

In the Office Action, the Examiner rejected Claims 1-9, 12-15, 17, 18, and 21 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,143,247, to Sheppard, Jr., et al. (hereinafter “Sheppard”). The Examiner rejected Claims 10 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Sheppard in view of U.S. Patent No. 5,812,419, to Chupp, et al. (hereinafter “Chupp”). Claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sheppard in view of U.S. Patent No. 4,307,367, to Miller, et al. (hereinafter “Miller”). Claims 19 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Sheppard. Claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Sheppard in view of U.S. Patent No. 5,962,238, to Sizto, et al (hereinafter “Sizto”).

Claim 1, as amended recites as follows:

1. A method of conducting an assay, the method comprising:
 - providing a sample of cells in a chamber in a disc, the chamber including at least one capture zone with a capture agent;
 - loading the disc into an optical reader;
 - rotating the disc so as to separate different cell types into different capture zones;
 - directing an incident beam of electromagnetic radiation to the capture zone;
 - detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone;
 - converting the detected beam into an output signal;
 - analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone;
 - counting captured cells in each of the capture zones; and
 - providing an output including the counts, wherein the output includes counts for CD4 cells and CD8 cells.

Applicant respectfully submits that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *See* M.P.E.P. § 2131. Furthermore, to establish a *prima facie* case of obviousness a

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three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicant respectfully submits that the cited prior art fails to teach or suggest all of the above-listed claim limitations. Furthermore, Applicant submits that there is no motivation or suggestion to combine the cited references as cited by the Examiner.

In the Office Action, the Examiner stated noted that Sheppard fails to teach a method of providing an output that includes the counts for CD4 and CD8 cells, but took the position that this was described in Sizto. Applicant notes that the particular section of Sheppard relied upon in the office action relates to a system for testing using rotatable disks. *See* Sheppard, col. 26, lines 52-62. In contrast, Sizto is directed to a system for scanning that uses scanner that moves longitudinally. Even if it were permissible to “pick and choose” from the teachings of Sizto, Appellant’s claimed invention is not made obvious by the combination of Sizto and Sheppard because using the scanner of Sizto in Sheppard range would change the principle of operation of the Sheppard system. Where the proposed modification of the prior art changes the principle of operation of the prior art invention being modified, the teachings of the references are not sufficient to render the claims *prima facie* obvious.¹ The embodiment of Sheppard relied upon is directed to a disk system—not longitudinal scanners. Applicant respectfully submits that the Examiner has failed to explain how these different types of systems could be modified to derive the claimed invention and where the prior art suggested this modification, and therefore has failed to provide a valid *prima facie* rejection. Applicant respectfully requests withdrawal of this rejection and allowance of this claim.

Since Claims 2-21, each depend on Claim 1, Applicant respectfully submits that they are allowable for the reasons discussed above and the subject matter of their own limitations.

¹ *See In re Ratti*, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959) (Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency).

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Discussion of Provisional Double Patenting Rejections

In the Office Action, the Examiner made a number provisional double patenting rejections. Applicant respectfully submits that this rejection will be addressed if these rejections become non-provisional.

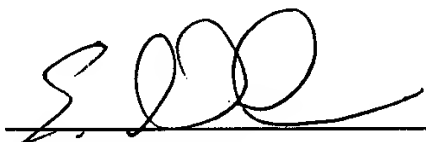
Summary

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims for patentability purposes, the reasons therefore, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, and the claims would satisfy the statutory requirements for patentability without the entry of such amendments. In addition, such amendments do not narrow the scope of the claims. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner has any questions which may be answered by telephone, he is invited to call the undersigned directly.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Oct. 18, 2001

By: 
Eric M. Nelson
Registration No. 43,829
Attorney of Record
Customer No. 20,995
(619) 235-8550

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AMENDMENTS TO THE DRAWINGS

Applicant has enclosed substitute drawings for Figures 1A, 1B, 1C, 2A, 2B, and 2C.



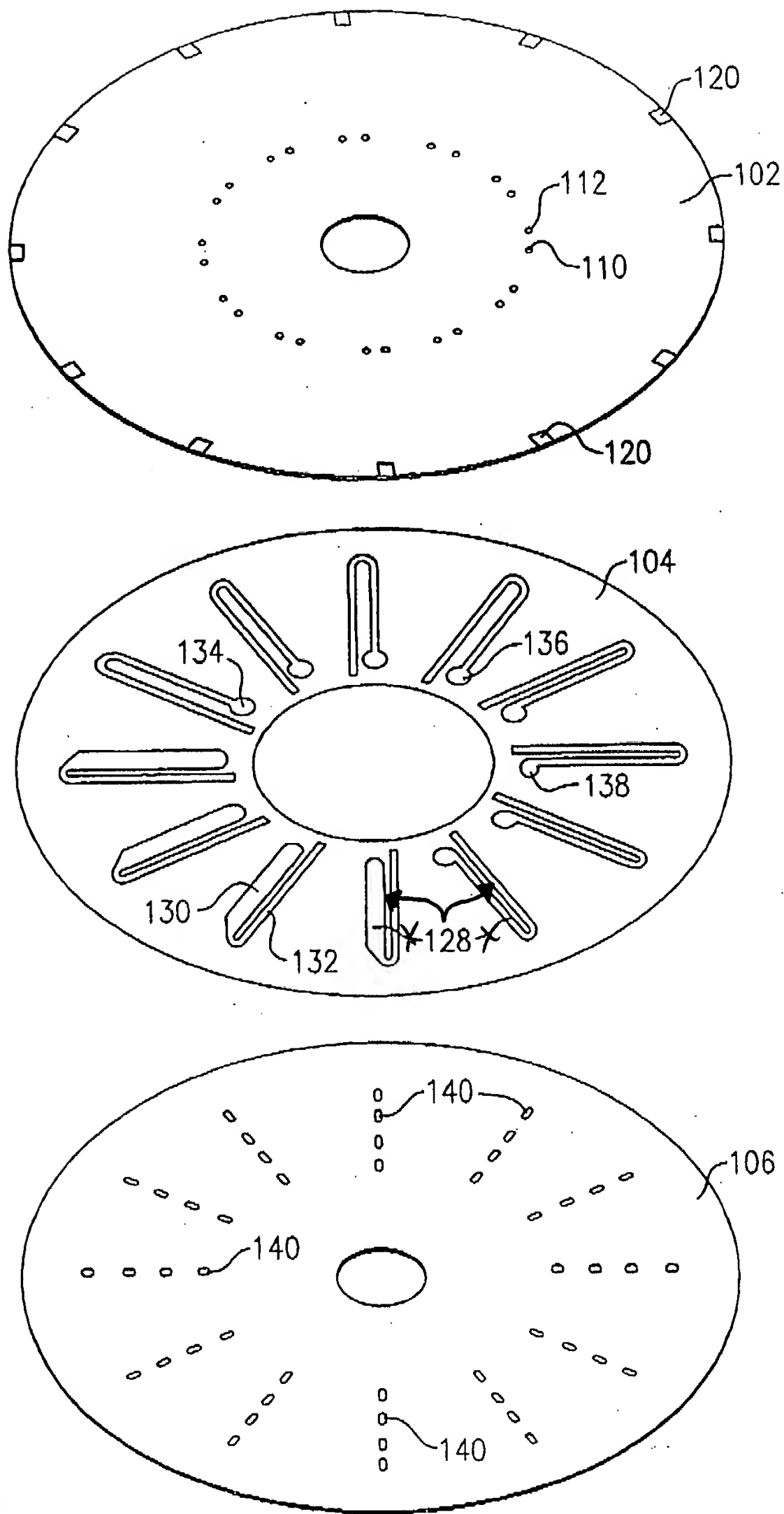
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FIG. 1A



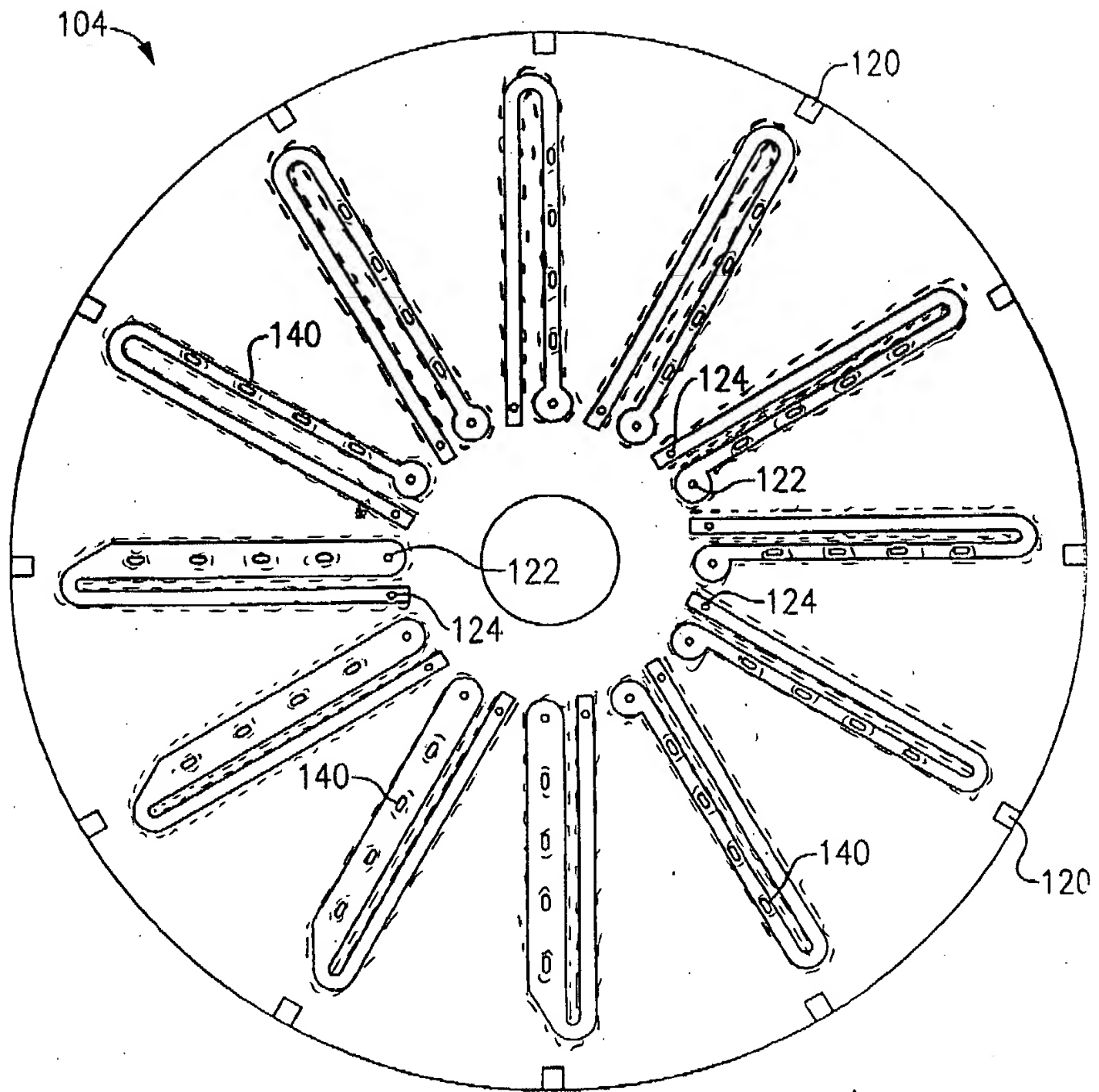


FIG. 1B

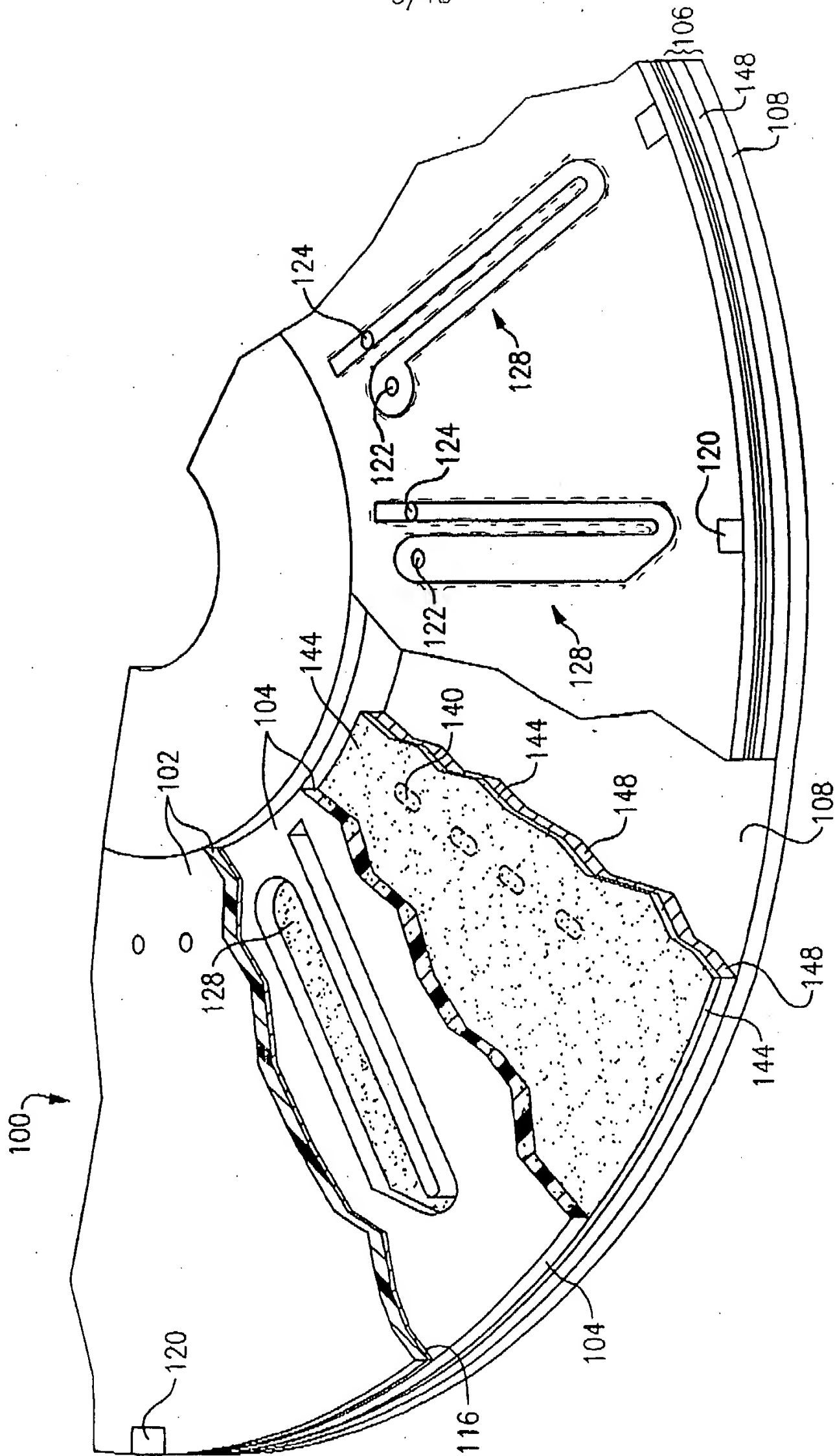
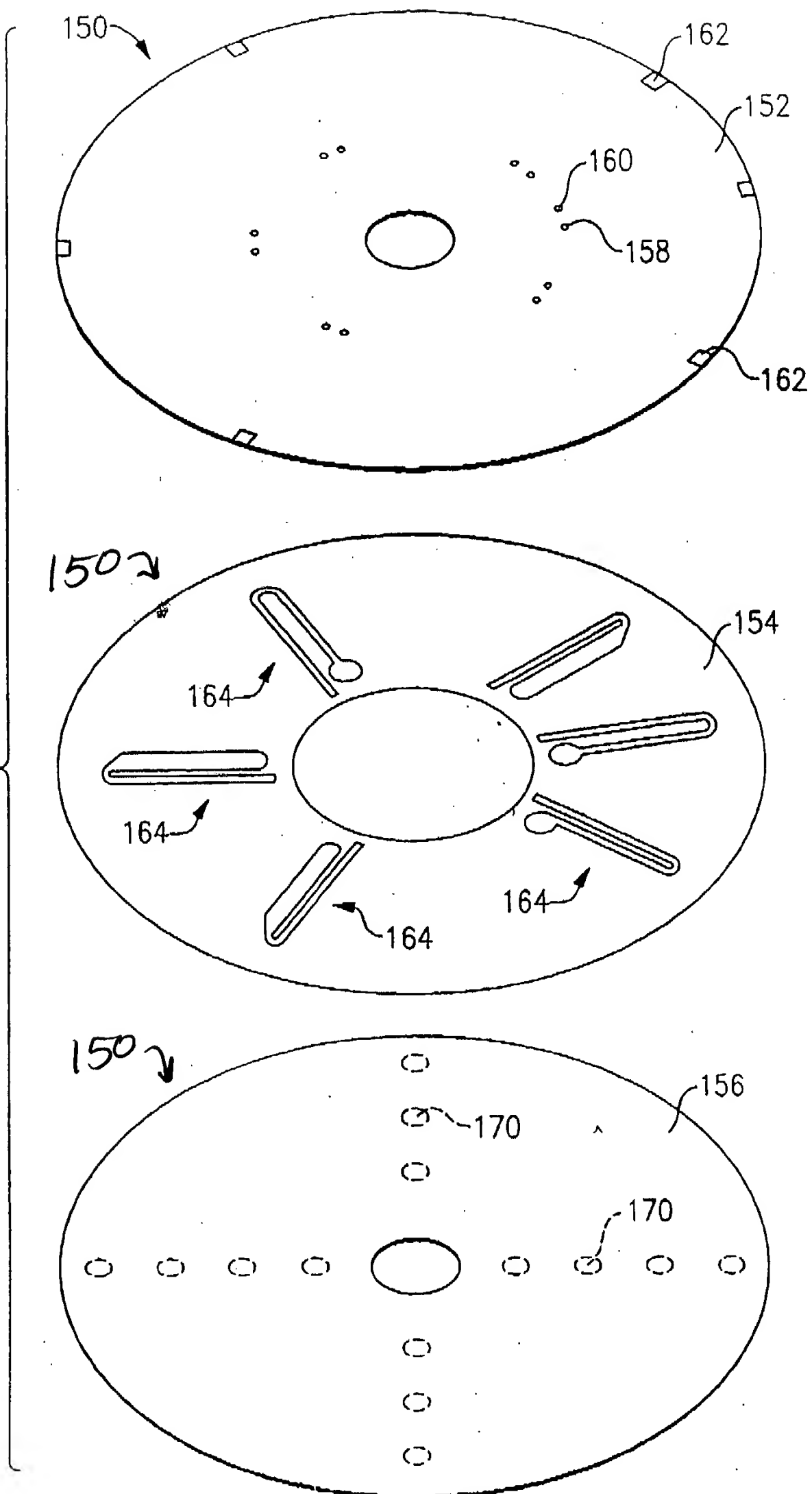


FIG. 1C

FIG. 2A



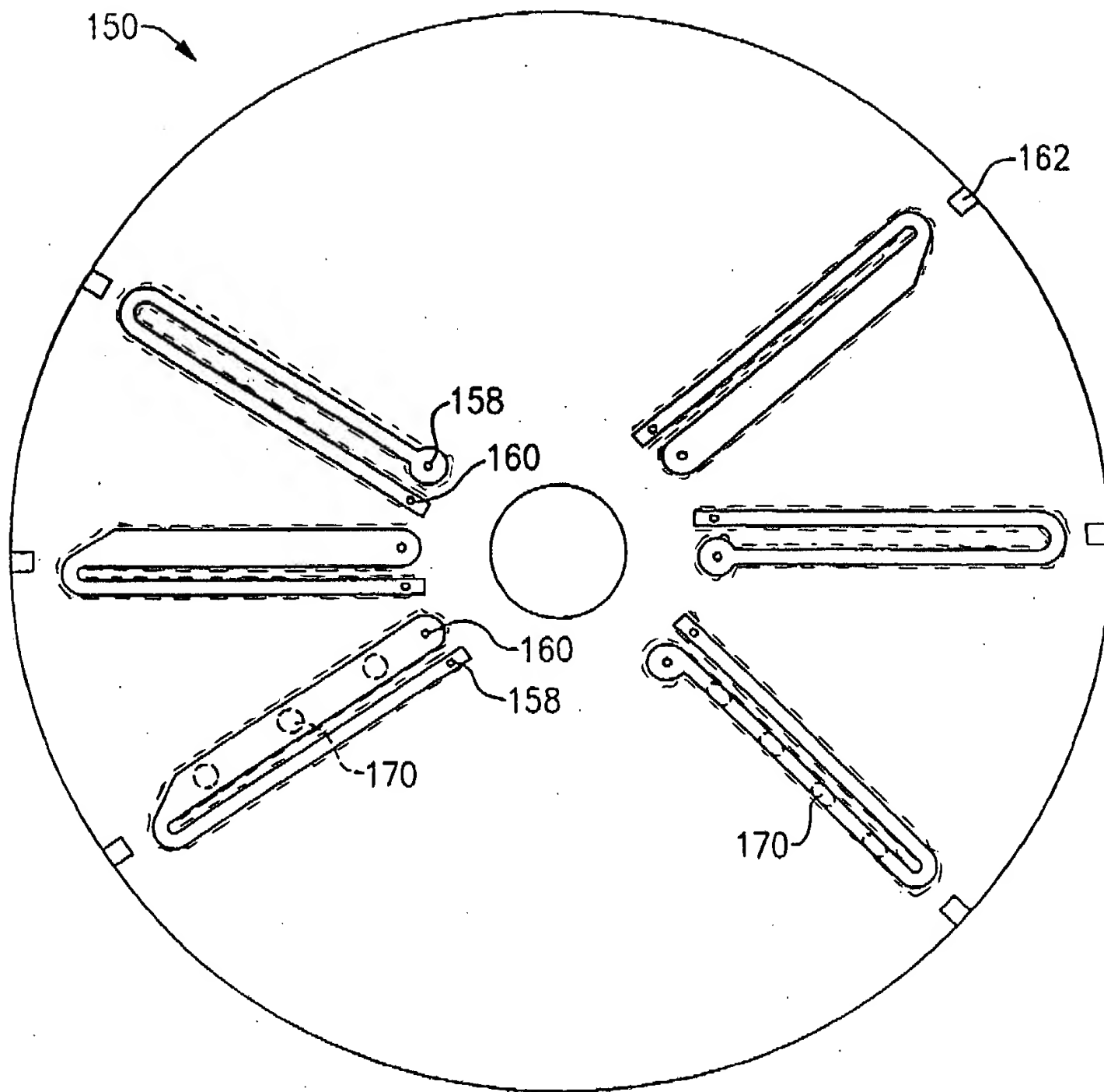


FIG.2B

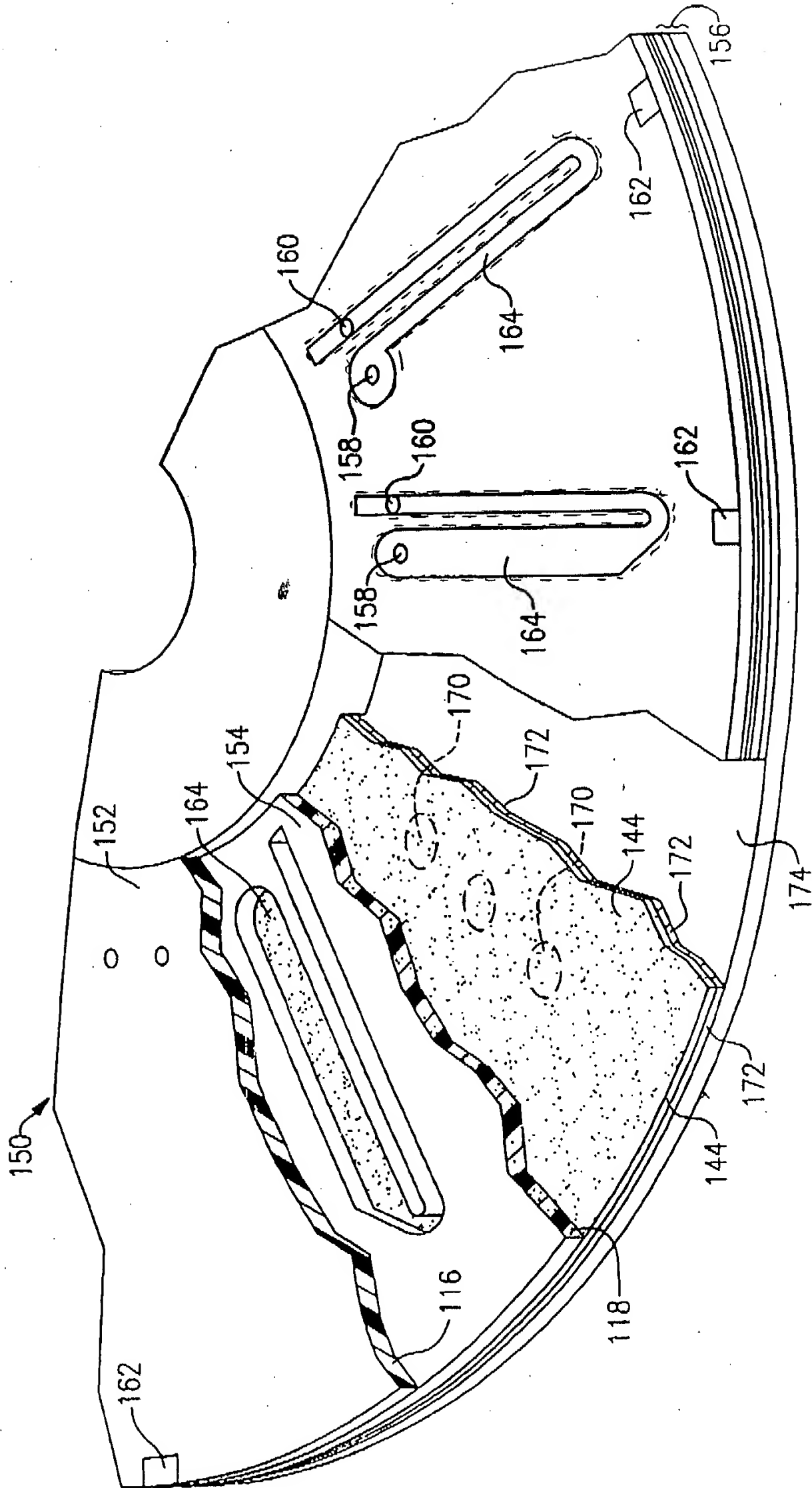


FIG. 2C